K112869

DEC 16 2011

# 510(k) Summary

**Summary Prepared Date:** 12/14/2011

**Submission Sponsor:**

**Beyes Dental Canada Inc.**
595 Middlefield Road Unit 9, Toronto, M1V 3S2 Canada

Mr. Ted Thompson
Toll Free: 1-877-703-3562
info@beyes.ca

**Submission Correspondent:**

Mr. Anthony Hopkins
Regulatory Affairs Specialist

Mr. Leon Lu
Director of Quality and Regulatory Affairs

**MEDevice Services, LLC**
3500 South Dupont Highway
Dover, Delaware 19901 USA
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**Trade/Device Name:**
EasyProphy Series Air Polish Devices,
Models EasyProphy 200 and EasyProphy 400

**Common or Usual Name:** handpiece, air-powered, dental
**Device Class:** I
**Classification Name:** handpiece, air-powered, dental
**Regulation Number:** 21 CFR 872.4200
**Product Code:** EFB
**Review Panel:** Dental

K112869

**Predicate Device:**

- K032395, Nakanishi, Incorporated
  Prophy-Mate

- K092289, Ems Electro Medical Systems Sa
  Ems Air-Flow Handy Perio

**Device Description:**

This device is a hand-held device that contains air and water lines, a capped chamber for the cleaning powder, and a nozzle. This device connects to a standard turbine tube that supplies air and water. When the Air Polisher is connected and activated, a stream comprised of powder, air, and water spray is generated. This spray can be directed on the tooth surface to clean and polish the tooth.

**Intended Use:**

The EasyProphy Series Air Polish Devices are intended for use in dental applications to remove stains and plaque deposits from the teeth by shooting a mixture of sodium bicarbonate powers, air, and water onto tooth surfaces.

**Comparison to Predicate Devices:**

The EasyProphy Series Air Polish Devices and the predicate device are used for cleaning and polishing of teeth. Both the proposed device and the predicate device connect to a standard turbine connection on a dental operative unit. Both deliver a mixture of water, air, and dental powder to a treatment site.

The EasyProphy Series Air Polish Devices is essentially the same as or similar to the predicate device in terms of the intended use, design and construction, performance characteristics, and materials. The patient contact materials used are well-known biocompatible, so no new issues of biocompatibility are raised with regard to this device.

**Discussion of Non-Clinical Tests Performed:**

Testing conducted demonstrates that the easyProphy Series Air Polish Devices fulfills the prospectively defined performance specifications.

Therefore, we conclude that the EasyProphy Series Air Polish Devices is both safe and effective for its intended use.

**Biocompatibility:**

The patient-contacting portions and waterline composition of the EasyProphy Series Air Polish Devices, Models EasyProphy 200 and EasyProphy 400 are made of type 304 Stainless Steel. Biocompatibility testing on the type 304 Stainless Steel was not performed as it is commonly used for implant device and other medical devices, and has a history of biocompatibility.

**Discussion of Clinical Tests Performed:**

None

**Conclusion:**

The EasyProphy Series Air Polish Devices as safe and effective as the predicate devices. The proposed device has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the proposed device and its predicate devices raise no new issues of safety or effectiveness. Thus, the EasyProphy Series Air Polish Devices, models EasyProphy 200 and EasyProphy 400 are substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Beyes Dental Canada Incorporated
C/O Mr. Anthony Hopkins
Regulatory Affairs Specialist
MEDevice Services, LLC
3500 South Dupont Highway
Dover, Delaware 19901

DEC 16 2011

Re: K112869
Trade/Device Name: EasyProphy Series Air Polish Devices, Models EasyProphy 200 and EasyProphy 400
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 25, 2011
Received: September 30, 2011

Dear Mr. Hopkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

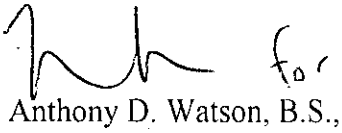
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety /ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112869

# Indications for Use

**510(k) Number (if known):**

Device Name:

EasyProphy Series Air Polish Devices, Models EasyProphy 200 and EasyProphy 400

**Indications for Use:**

The EasyProphy Series Air Polish Devices are intended for use in dental applications to remove stains and plaque deposits from the teeth by shooting a mixture of sodium bicarbonate powers, air, and water onto tooth surfaces.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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